

4. (Amended) A specimen cup as in Claim 1, wherein said cassette is integrated with said container through inserting said cassette into custom channels on said container to anchor said cassette's outside edges and orient cassette for proper testing and viewing.

5. (Amended) A specimen cup as in Claim 1, wherein said cassette comprises test strips used to test for THC, COC, MAP, PCP and MOR.

6. (Amended) A specimen cup as in Claim 1, wherein said cassette comprises a plurality of isolated test channels which house said test strip for testing drugs of abuse.

9. (Amended) A specimen cup as in Claim 1, further comprising a flap to which once fluid specimen entered into said cup, said flap will prevent said fluid specimen from splashing during collection, testing, transport and storage.

10. (Amended) A specimen cup as in Claim 1, further comprising a floating member configured to substantially fill a volume directly above said fluid specimen once said fluid specimen is entered into said cup, said floating member being configured to prevent said fluid specimen from splashing during collection, testing, transport and storage.

16. (Amended) A specimen cup as in Claim 1, further comprising a dam structure attached to said cassette in order to form a recessed pooling area in said cassette wherein said cassette is configured to draw said testing fluid specimen from said cassette's end portion through said a pooling area the pooling area being configured to expose said cassette's interior test strips to the fluid specimen, while recessed the exposed portion of said test strips sufficiently to minimize potential contamination of the test strips.

REMARKS

Rejections Under 35 U.S.C. §112

The Examiner has rejected Claim 10 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

The Examiner has found that Claim 10 is vague and indefinite as to what structure is intended by a "float" that will prevent splashing during sample application. In response, Applicant has amended Claim 10 to recite "a floating member configured to substantially fill a volume directly above said fluid specimen once said fluid specimen is entered into said cup, said

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floating member being configured to prevent said fluid specimen from splashing during collection, testing, transport, and storage.”

Accordingly, Applicant submits that the rejections for indefiniteness are overcome.

Rejections Under 35 U.S.C. §102

The Examiner has rejected Claims 1, 4-8, 10 and 16 as being clearly anticipated under both 35 U.S.C. § 102(b) and (e) by PCT application WO 97/33519 (Cipkowski) (WO '97 hereafter) or by U.S. Patent No. 5,916,815 (Lappe). Although the specification provided a meaning of “custom fit” by providing embodiments in which the test cassette was integrated with the container itself, rather than only with the lid as in the asserted prior art, for clarity and to speed prosecution Applicant has chosen to amend Claim 1. The amended Claim 1, upon which Claims 2-16 depend, reciting a cassette “custom integrated with said container” more precisely reflects the intended meaning of “custom fit” as supported by the specification and further distinguishes the present invention from the prior art asserted by the Examiner. Claim 1, as amended, recites a “cup comprising a container used to collect a fluid specimen, a container lid, a cassette hermetically sealed and custom integrated with said container.” Claim 4 has also been amended to reflect the changes to Claim 1. An example of this integration is described in the specification and in Claim 4, through the configuration of a container having custom channels into which the cassette is slid in order to properly orient the cassette within the container.

The asserted prior art, in contrast, teaches nothing about a cassette which is integrated with the container itself. Rather, the references teach the attachment of a card to the lid of the container, not to the walls of the container itself, in order to perpendicularly suspend the card from the lid into the container below. WO '97 teaches a drug abuse kit comprising a container 11 having a closure cap 22 with a slit 19 configured to receive a drug test card 25 (pp. 7-8; Fig. 1-2). The disclosed drug test card 25 is only shown integrated with the cap 22 by means of inserting the card 25 through the slit 19, not through integration with the container 11 itself. Similarly, Lappe teaches a drug assay system comprising a collection cup 10, a lid 18, and a test card 22 affixed perpendicular to the collection cup lid 18 and extending downward into the collection cup 10. As in WO '97, the test card 22 in Lappe is only shown integrated with the lid 18, not through integration with the cup 10 itself. In both asserted references the attachment of

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the test card to the container lid only allows a test card to be suspended within a specimen container.

No form of integration with the surrounding container is provided and, as a result, in the asserted prior art the test card is not necessarily precisely oriented within the container (e.g., with respect to a sloped floor or viewing window), as the present invention's configuration ensures. Neither asserted prior art references discloses the present inventions feature of custom integrating a test cassette with the container itself, rather than the lid. As a result, Applicant submits that the rejection of newly amended Claim 1 and Claims 2-16, which depend on Claim 1, over the art of record, are overcome.

With specific regard to Claim 16, Applicant submits that the asserted prior art does not teach a cassette having a pooling area which is sufficiently recessed to minimize contamination of the internal test strips through contact with the outside sources, such as the surrounding environment or a lab technician handling the cassette, while still allowing exposure of the wicking portion of the test strip to the fluid specimen. Although Applicant believes the definition of pooling area is sufficiently supported by the specification (*See*, '429 Application at p. 7, ll. 6-15), Applicant has chosen to amend Claim 16 in order to speed prosecution and clarify the intended meaning of "pooling area." Also, as mentioned earlier, Figure 3 has been corrected in order to label this "pooling area 210." As a result, Applicant submits that the Examiner's objections to Claim 16 are overcome.

Accordingly, Applicant submits that the art of record does not teach or suggest each of the recited features in the claims as amended, and that the amended claims are accordingly allowable over the art of record.

Rejections Under 35 U.S.C. §103

The Examiner has rejected Claims 2-3, 9 and 11-15 as being unpatentable under 35 U.S.C. § 103(a) over two primary references (Cipkowski, Lappe) that taught a specimen cup having a test card integrated with the cup lid, in view of a secondary reference (Davis) that taught the use of a cup lid having a conical sloped floor designed to channel fluid to a drain leading back into the container portion of the specimen cup.

In particular, the Examiner has rejected Claim 2 over Cipkowski (PCT application WO 97/33519)(WO '97 hereafter) and Lappe (U.S. Patent No. 5,916,815), further in view of Davis

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(U.S. Patent No. 5,119,830). For some reason, which is not clear from the communication, the Examiner has again rejected Claim 2, and also Claims 3, 9 and 11-15 over the same combination of prior art, namely Cipkowski (PCT application WO 97/33519) or Lappe (U.S. Patent No. 5,916,815), further in view of Davis (U.S. Patent No. 5,119,830). Applicant asks the Examiner to clarify the distinct rationales of both rejecting Claim 2 over WO '97 and Lappe, further in view of Davis and, also, rejecting Claim 2 over WO '97 or Lappe, further in view of Davis. See Office Action at pp.4-5.

Applicant respectfully submits that the Examiner failed to properly ascertain the differences between the prior art and the present invention for the purposes of an obviousness determination and, in addition, failed to prove a *prima facie* case of obviousness. Applicant asks that the Examiner reconsider the obviousness rejection based on the existing specification and the amended claims. A determination of obviousness requires ascertaining the differences between the prior art and the claims at issue. See Graham v. John Deere Co., 148 U.S.P.Q. 459, 467.

Applicant respectfully submits that the Examiner has not properly considered the differences between the asserted prior art and the claimed invention. None of the primary references taught or suggested the integration of a test cassette with the container itself. Rather, the prior art asserted only integrating the test card with the container lid. As discussed earlier, although the specification provided a meaning of "custom fit" by providing embodiments in which the test cassette was integrated with the container itself, Applicant has chosen to amend Claims 1 and 4 for clarity. The amended Claim 1, upon which Claims 2-16 depend, more precisely reflects the intended meaning of "custom fit" as supported by the specification and further distinguishes the present invention from the prior art asserted by the Examiner. Claim 1, as amended, recites a "cup comprising a container used to collect a fluid specimen, a container lid, a *cassette* hermetically sealed and *custom integrated with said container (emphasis added)*."

As described in the specification and in the amended claims, the claimed specimen cup comprises a cassette which is custom integrated with the container, through such configurations as custom channels into which the cassette is slid in order to properly orient the cassette within the container. These channels can be configured so that the cassette will only fit if properly oriented. See '656 Application at p. 6. The asserted prior art, in contrast, teaches neither a test cassette which is integrated with the container itself, nor a configuration which ensures a test

cassette is properly oriented. Rather, the primary references teach the attachment of a card to the lid of the container, not to the walls of the container itself, so that the card protrudes perpendicularly from the lid into the container. The secondary reference, Davis, does not even teach protruding the test card into the container, but rather a chemical test strip 24 is parallel oriented with the top surface of the lid main member 22 (Col. 3, lines 18-20; Fig.1). The WO '97 reference teaches a drug abuse kit comprising a container 11 having a closure cap 22 with a slit 19 configured to receive a drug test card 25 (p. 7-8; Fig. 1-2). The disclosed drug test *card* of WO '97 is *only* shown *integrated with the cap* by means of the slit, not through integration with the container itself. Similarly, Lappe teaches a drug assay system comprising a collection cup, a lid, and a test card affixed perpendicular to the collection cup lid 18 and extending downward into the collection cup. As in WO '97, the test card in Lappe is *only shown integrated with the lid*, not through integration with the cup itself. In both asserted references the attachment of the test card to the container lid only allows a test card to be suspended within a specimen container. No form of integration with the surrounding container is provided and, as a result, in the asserted prior art the test card cannot be as precisely oriented with respect to the base container, as is made possible with the custom integration of the present invention. Such substantial structural differences renders the asserted prior art incapable of supporting an obviousness rejection of the claims as amended.

With particular reference to Claim 2, the Examiner has asserted that the secondary reference's (Davis) teaching of a cup *lid* 14 having a *conical sloped floor* 34 designed to channel fluid to a valve shell 46 or *drain* leading back into the base container 12 of the specimen cup is sufficiently equivalent to the structure recited in Claim 2 of the present invention. *See*, Davis, Col. 5, lines 28-38; Figure 6-7. In contrast, the present invention recites a specimen cup having a *container* floor which is *uniformly sloped* across its face. In addition, the purpose of the present invention's uniformly sloped floor of guiding a fluid specimen to adequately *contact* the wicking portion of the test cassette and thus allow an otherwise inadequate volume of fluid specimen to be tested. *See*, '429 application, Claim 2, p. 6, ll. 14-16. Consequently, Applicant submits that the respective design and purpose of the recited sloped lid floor of Davis is in no way similar to the uniformly sloped container floor of the present invention. Davis' conical sloped lid floor configured for draining purposes, does not provide a feature which suggests the present invention's non-conical sloped container floor, configured for improved low volume specimen

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testing. The only commonality of the two structures is that they can, speaking in broad terms, both be labeled as sloped features in general. Applicant respectfully submits that the Examiner avoid a cursory analysis of the structure and, instead, reexamine the features of the asserted prior art and the claimed invention with regard to the location of each sloped feature, the geometry of the slope itself, and the purpose of each sloped feature.

Applicant respectfully submit that the art of record does not present a *prima facie* case of obviousness. Thus, the Examiner has not provided any particular teaching from the prior art which suggests a motivation to combine the references in the manner asserted. A *prima facie* showing of obviousness requires a teaching or suggestion from the prior art to combine the references in the manner asserted. "Before the PTO may combine the disclosures of two or more prior art references in order to establish *prima facie* obviousness, there must be some suggestion for doing so, found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art." *In re Jones*, 21 U.S.P.Q.2d 1941, 1943-44 (Fed. Cir. 1992).

Rather than such a suggestion, Applicants submit that the Examiner has sorted through the prior art and merely attempted to present and combine selected references which individually contain a vaguely related feature of the present invention. Thus, the Examiner has cited primary references (WO '97 and Lappe), which merely suspend a test card from a lid into a container rather than integrating and orienting a test cassette with a base container through attachment to the container itself, as rendering the present invention's "custom fit" (amended for clarity to read "custom integrated") obvious. In addition, the Examiner has asserted that the secondary reference's (Davis) teaching of a cup lid, having a conical sloped floor designed to channel fluid to a drain leading back into the base container, renders the present invention's structure. As recited in Claim 2 and in the specification, the present inventions structure comprises a specimen cup having a container floor which is sloped for the purpose of guiding a fluid specimen to adequately contact the wicking portion of the test cassette and thus allow an otherwise inadequate volume of fluid specimen to be tested (p. 6, ll. 14-16). Even if each feature found in the asserted prior art is present in the recited invention, as recognized by the Federal Circuit,

If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue. Furthermore, rejecting patents solely by finding prior art corollaries for the claimed elements would permit an

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examiner to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat the patentability of the claimed invention.

In re Rouffet, 47 U.S.P.Q.2d 1453, 1457 (Fed. Cir. 1998). Applicants submit that the Examiner has inadvertently fallen prey to exactly this hindsight trap, whereby the Examiner picks and chooses elements from various prior art devices using only Applicants' own invention as a guide in the selection of the various elements. "It is impermissible, however, simply to engage in a hindsight reconstruction of the claimed invention, using the applicant's structure as a template and selecting elements from references to fill the gaps." In re Gorman, 18 U.S.P.Q.2d 1885, 1888 (Fed. Cir. 1991). Of additional relevance to Applicant's present invention, the avoidance of applying hindsight methodology "is especially important in the case of less technologically complex inventions, where the very ease with which the invention can be understood may prompt one 'to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher'". In re Dembiczak, 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999) (citing, W. L. Gore & Assoc., Inc. v. Garlock, Inc., 220 U.S.P.Q. 303, 313).

Contrary to the Federal Circuit's admonishment to present *evidence* of a suggestion, teaching or motivation to combine, the Examiner presents only conclusory statements. The Examiner states that the claimed flat face is obvious because it achieves the "well known and predictable results of bringing the results closer to permit better viewing by people with poor eyesight." Office Action at p.5 The Examiner neither offers any reference relating to specimen cups which discloses this advantage, nor considers the particular advantages of flat faced configuration, which Applicant has discovered. For instance, Applicant has designed the specimen cup so that the container is still round in order to ease handling and maintain stability, while having a flat face which allows the test cassette to be more easily viewed. '429 Application at p. 3, ll. 16-18. Applicant has also spaced the flat face of the container from the test cassette so that air flow between the two is allowed, thus reduced view distorting condensation. '429 at p.6, ll. 27-29.

Further disregarding the need to present evidence, the Examiner states that because Davis employs a sloped floor (actually a lid having a conical sloped floor leading to a drain) and because sloping is "very effective for fluid control" and is "inexpensive to manufacture, simple and minimizes the chance of clogging" then the claimed invention is rendered obvious. Office Action at p. 4. In addition, the Examiner considers the one-way valve feature as "convention"

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and rendered obvious by being a "well-known and expected advantage of preventing the sample from contacting the technician." Office Action at p. 6. No evidence of these conclusory statement is provided. Such "[b]road conclusory statements regarding the teaching of multiple references, standing alone, are not 'evidence.'" *In re Dembiczak*, 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999).

Moreover, even if some suggestion existed to combine the references in the manner suggested by the Examiner, Applicant submits that the skilled artisan would not have arrived at a configuration of a claimed invention having each and every feature of the claimed invention.

None of the asserted references contain any teaching or suggestion with regard to a specimen cup having a test cassette custom integrated with the container itself. Furthermore, none of the asserted references teach or suggest the elements added in Applicant's dependent claims, which recite combining a specimen cup having a test cassette custom integrated with the container, with either a one-way valve/float, a flat viewing face, a contaminant resistant recessed pooling area, or a sloped container floor. Nor has the Examiner presented any suggestion to combine these elements from the prior art.

Accordingly, Applicant submits that the amended claims are patentable over the art of record, in accordance with 35 U.S.C § 103(a).

Additional Amendments

Claims 5, 6, and 9 have also been amended only to correct inadvertent typographical errors, while Claims 1 and 10 have also been amended for inadvertent typographical errors, in addition to the aforementioned reasons under the above §102 and §103 analysis's. These typographical amendments do not add any new matter and, as a result, Applicant respectfully requests that the Examiner allow these corrections.

CONCLUSIONS

In view of the foregoing amendments and remarks, Applicant respectfully submits that the application as amended is in condition for allowance and respectfully requests the same. If, however, some issue remains that the Examiner feels can be addressed by Examiner's Amendment, the Examiner is cordially invited to call the undersigned for authorization.

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typographical amendments do not add any new matter and, as a result, Applicant respectfully requests that the Examiner allow these corrections.

CONCLUSIONS

In view of the foregoing amendments and remarks, Applicant respectfully submits that the application as amended is in condition for allowance and respectfully requests the same. If, however, some issue remains that the Examiner feels can be addressed by Examiner's Amendment, the Examiner is cordially invited to call the undersigned for authorization.

Attached hereto is a separate paper entitled VERSION OF THE AMENDMENTS SHOWING CHANGES MADE, in which additions are shown in double underlining and deletions are shown ~~stricken through~~.

Respectfully submitted,

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VERSION SHOWING CHANGES MADE TO THE CLAIMS

Claims 1, 4-6, 9, 10, and 16 have been amended as indicated below.

1. (Amended) A specimen cup for testing fluid specimen contained therein, said cup comprising a container used to collect a fluid specimen, a container lid, a cassette hermetically sealed and custom ~~fit to~~ integrated with said container, said cassette further containing chemical strips means to provide an indication of a characteristic of said specimen regarding drugs of abuses.

2. A specimen cup as in Claim 1, wherein said bottom floor of said cup is sloping from the backside downwardly at 1-3° towards the front side allowing specimen to be channeled towards testing device.

3. A specimen cup as in Claim 1, wherein said cup has a retracted flat face designed to move the viewing area closer to said cassette.

4. (Amended) A specimen cup as in Claim 1, wherein said cassette is integrated with ~~inserted into~~ said container through inserting said cassette into custom channels on said container to anchor said cassette's outside edges and orient cassette for proper testing and viewing.

5. (Amended) A specimen cup as in Claim 1, wherein said cassette ~~comprising~~ comprises test strips used to test for THC, COC, MAP, PCP and MOR.

6. (Amended) A specimen cup as in Claim 1, wherein said cassette ~~comprising~~ comprises a plurality of isolated test channels which house said test strip for testing drugs of abuse.

7. A specimen cup as in Claim 6, wherein each isolated test channels has a clear, sealed window hermetically sealed to face of cassette for viewing the results of the test.

8. A specimen cup as in Claim 7, wherein said clear, sealed window is formed by a transport fluid-resistant sheet laying on top of said test strips to prevent fluid specimen from accidentally spill and contaminate the strips.

9. (Amended) A specimen cup as in Claim 1, ~~wherein said cup~~ further comprising a flap to which once fluid specimen entered into said cup, said flap will prevent said fluid specimen from splashing during collection, testing, transport and storage.

10. (Amended) A specimen cup as in Claim 1, ~~wherein said cup~~ further comprising a floating member configured to substantially fill a volume directly above said fluid specimen to ~~which~~ once said fluid specimen is entered into said cup, said floating member being configured to ~~will~~ prevent said fluid specimen from splashing during collection, testing, transport and storage.

11. A specimen cup as in Claim 1, wherein said cup is construed of a material selected from the group comprising thermoplastics, specialty plastics, thermosets, and engineering plastics.

12. A specimen cup as in Claim 10, wherein said thermoplastics is selected from the group comprising polyamideimide (PAI), polyethersulfone (PES), polyarylsulfone (PAS), polyetherimide (PEI), polyarylate (PAR), polysulfone (PSO), polyamide (PA), polycarbonate (PC), styrene-maleic anhydride (SMA), chlorinated PVC (CPVC), poly(methylmethacrylate) (PMMA), styrene-acrylonitrile (SAN), polystyrene (PS), acrylonitrile-butadiene-styrene (PS), acrylonitrile-butadiene-styrene (ABS), poly(ethyleneterephthalate) (PET), poly(vinylchloride) (PVC), polyetherketone (PEK), polyetheretherketone (PEEK), polytetrafluoroethylene (PTFE), poly(phenylene sulfide) (PPS), liquid crystal polymer (CCP), nylon-6,6, nylon-6, nylon-6,12, nylon-11, nylon 12, acetal resin, low and high density propylene (PP), high density polyethylene (HDPE), low density polyethylene (LDPE), polystyrene, ethylene-vinyl acetate, poly-vinyl-acetate and polyacrylic.

13. A specimen cup as in Claim 10, wherein said specialty plastics is selected from the group comprising fluorocarbon polymers and infusible film products, and Upilex polyimide film.

14. A specimen cup as in Claim 10, wherein said thermosets is selected from the group comprising phenolics, epoxies, urea-formaldehyde and silicones.

15. A specimen cup as in Claim 10, wherein said engineering plastics is selected from the group comprising acetyl resins, polyamide, polyetherimides, polyesters, liquid crystal polymers, polycarbonate resins, poly(phenylene ether) alloys, polysulfone resins and polyamideimide resins.

16. (Amended) A specimen cup as in Claim 1, further comprising a dam structure attached to said cassette in order to form a recessed pooling area in said cassette wherein said cassette is configured to draw said testing fluid specimen from said cassette's bottom end portion

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through said a pooling area the pooling area being configured to expose said cassette's interior test strips to the fluid specimen, while recessed the exposed portion of said test strips sufficiently to minimize potential contamination of the test strips.

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